

The Story and The Learnings of The Great Ventilator Rush of 2020

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This time last year...

- In March 2020, LibrePlanet was quickly virtualized in response to the pandemic. This was a hair-on-fire emergency.
- At that time, there was much we didn't know:
 - We didn't know that social distancing would work or that people would comply with it.
 - We didn't know how to treat the disease.
 - Based on Northern Italy, it was entirely plausible that 1.5 million Americans would soon die because of COVID-19.
 - Through a combination of positive action and negligence, we clamped that down to 500,000 fatalities over the last year.

About Ventilators...

- In 2020 there was predicted to be a massive shortfall of ventilators globally.
- Over 100 teams started working on FLOSS ventilators.
- By June, doctors had learned that early ventilation was not as helpful as previous diseases had taught them.
- Ford, Tesla, and Dyson made tens of thousands of ventilators.
- Social impetus began to fade.

This talk is about what happened in the Free-Libre Open Source Ventilator Rush of 2020 and what we learned from it.

But also about a Vision:

“Twenty years from now, medical devices will be abundant because there will be an internationally distributed supply chain of transparently and publicly testable free culture medical devices.”

Structure of Talk

- The story of Ventilators in the Pandemic
- The learnings for FLOS hardware teams
- The composable approach we are taking
- Introducing the beginning of a new free culture license for medical devices

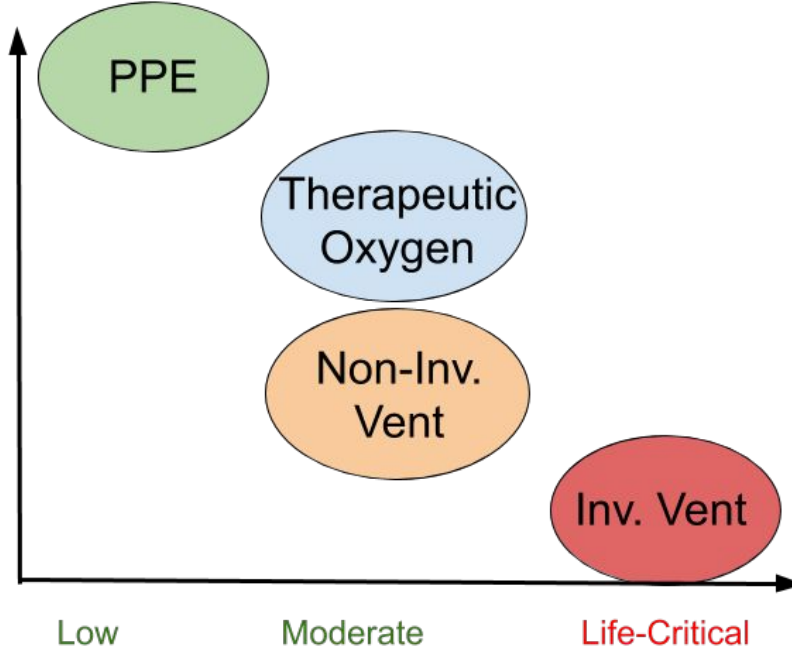
HUMANITARIAN ENGINEERING/MAKER WAYS TO HELP

% PERSONS
NEEDING
(LOG SCALE)

~100%

~10%

~1%



Low

Moderate

Life-Critical

RISK AND DIFFICULTY

Analysis of Open Source COVID-19 Pandemic Ventilator Projects

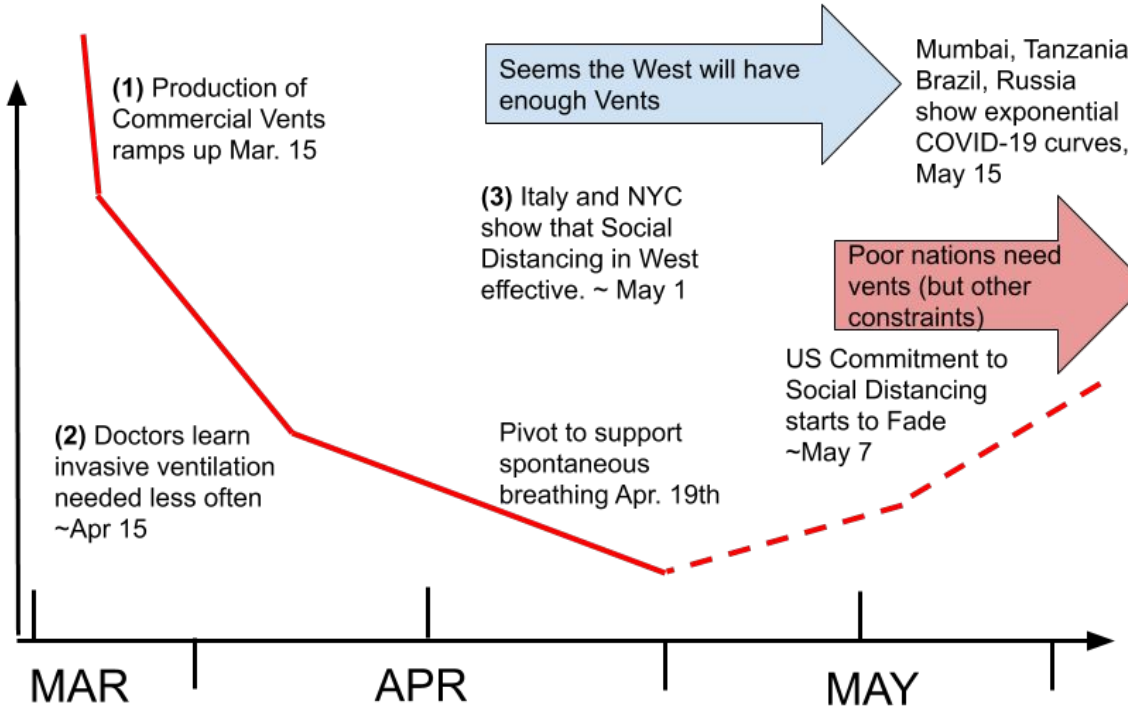
Look Down! We've added tabs for modules to encourage modularity!

Rank by Average

April 15, 2020	Public Invention	https://www.pubinv.org	Home Repo:	https://github.com/PublInv/covid19-vent-list										
Link to definition of evaluation criteria:	https://docs.google.com/document/d/e/2PACX-1vRI9yZ27KvsIftcNvweHGH1A81pO8gHL62TWpY_VY-UeLWdK9x-4-3hNw3DbkemClzExPsg8RfnxiiP/pub													
Project Name	Project Link	Openness	Buildability (1 unit)	Community Support	Functional Testing	Reliability Testing	COVID-19 Suitability	Clinician Friendly	Average	Manufacturability (1000s)	Date Last Evaluated	Point of Contact	Team Needs	Drive
Ambovent	https://1nn0v8ter.rocks/AmboV	5	5	5	4	3	4	4	4.29	3	2020-05-15	dreliam@gmail.com		AmbuB
Medtronic Puritan Bennett (PB) 5	http://newsroom.medtronic.com	4	2.5	4	5	5	4	5	4.21	4	2020-04-19			Pump
MUR (Minimal Universal Respirator)	https://www.mur-project.org/	4	4	4	3.5	4	3.5	3.5	3.79	2.5	2020-04-19	https://www.mur-project.org/		Pressu
Open Source Ventilator Project	https://simulation.health.ufl.edu	4	3.5	5	3.5	2.5	4	3.5	3.71	4	2020-04-19	https://simulation		Bellows
Rice OEDK Design: ApolloBVM	http://oedk.rice.edu/apollobvm/	5	4	4	2.5	2.5	3	2.5	3.36	2.5	2020-04-19	amy.k@rice.edu		AmbuB
A.R.M.E.E. Ventilator	www.armeevent.com	5	5	4	2	3	2	2.5	3.36	5	2020-04-19	warrenkoch@gmail.com		Pnuem
COVID-19 Rapid Manufacture Ve	https://www.instructables.com/	5	4	4	3	0	3.5	3.5	3.29	2.5	2020-04-19	https://www.instr		AmbuB
OpenVentilator (PopSolutions)	https://www.popsolutions.co/en	5	3.5	4	3.5	3	2	2	3.29	3	2020-04-08	contact@openve		Bellows
Low-Cost Open Source	https://github.com/jcl5m1/venti	5	4	4	3	1	3	3	3.29	3	2020-04-19	https://github.com		Pump
DIY-Beatmungsgerät [Respirator]	https://devpost.com/software/d	5	4	3	2.5	2	3	3	3.21	0	2020-04-19	https://docs.goo		AmbuB
MakAir	https://github.com/makers-for-i	4.5	2.5	5	3	2	2	3	3.14			quentin.adam@c		
OperationAIR	https://www.operationair.org/	4	4	4	3	2	3	2	3.14		2020-05-05	info@operational		Mass F
PREVAIL NY	https://jmawireless.com/prevail	4.5	4	3	2.5	0	4	3.5	3.07	3.5	2020-04-19	customerservice@		AmbuB
VentilAid	https://www.ventilaid.org/	5	4	4	3	0	2.5	2.5	3.00	2.5	2020-04-08	media@urbicum.		Bellows
CoroVent	https://www.corovent.cz/	3.5	2.5	4	4	0	3.5	3.5	3.00		2020-04-10	simon.rakosnik@		Bellows
Flow-i Bridge Project	https://grabcad.com/library/flow	4	2.5	3	2	2	3.5	4	3.00		2020-04-25		clinical validation	Servo (
Prototy Team OxyGEN	https://oxygen.prototy.xyz/	5	4	4	3	1	2	1	2.86	3	2020-04-19	https://www.oxy		AmbuB

Over 100 somewhat open-source ventilator projects right now...
 a better way to use thousands of skilled engineers is to modularize the problem.

NEED FOR PANDEMIC VENTILATORS



Chaos! ~Mar. 7

100 isolated teams start ~Mar. 15

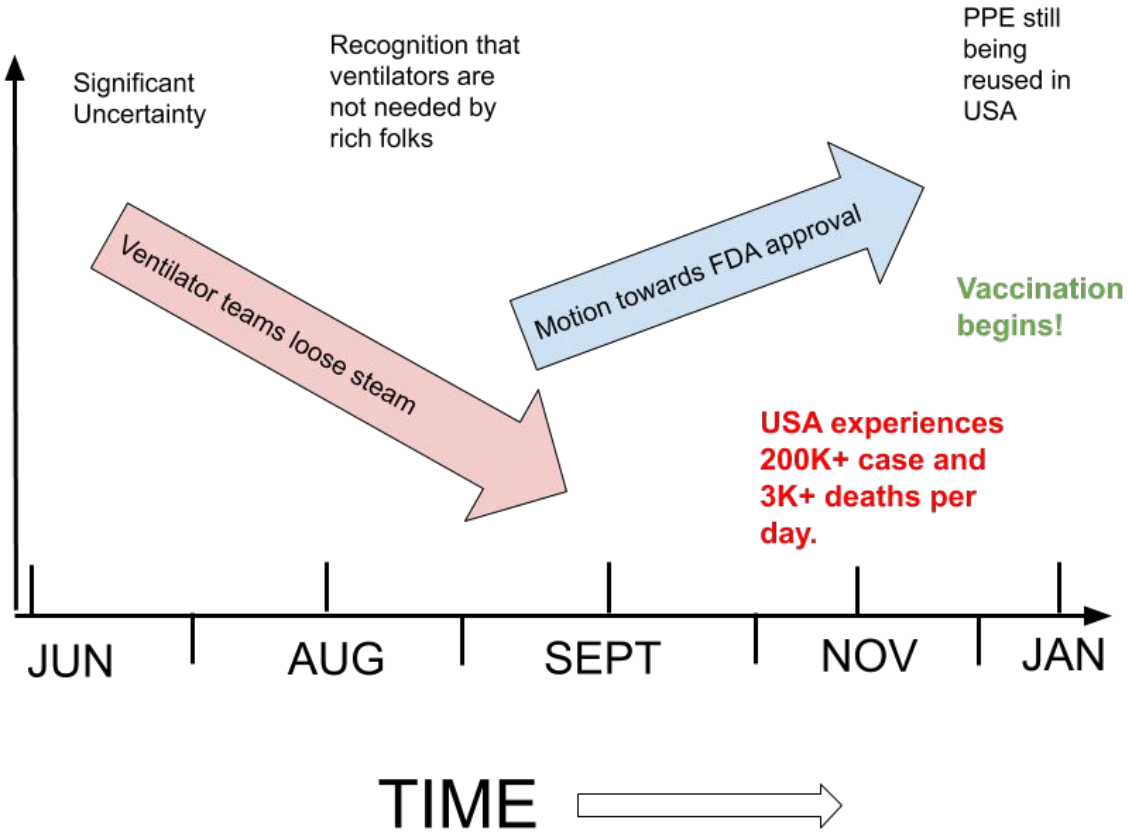
AmboVent fully opened Apr. 1

Consortia become well organized

Pivot to support spontaneous breathing Apr. 19th
Maker community succeeds in DIY PPE, ~May 1

US gives Vents to Russia, May 7

TIME →



?

2021

The Results: Mixed.

- Free-libre Open Source PPE was a successful (> 5 million pieces delivered)
- FLOS Ventilators mostly failed to have impact:
 - Some designs went closed-source and went dark
 - Some achieved Emergency Use Authorization
 - None have been used?
- But...
- New communities created
- Enormous spread of medical knowledge to engineers
- ...and an idea emerging of a libre respiration device ecosystem

New Communities Created

- Approximately 90,000 lightly involved volunteers
 - 70,000 at OSMS
 - 18,000 at Helpful Engineering
 - 100 active at COSMIC (but active)
 - 30 (active) at Public Invention
- A smaller number of people (100s)? who put in 100s of hours
- Five major organizations are (mostly) devoted to open source

Helpful Engineering

<https://helpfulengineering.org/>

Open Source Medical Supplies

<https://opensourcemedicalsupplies.org/>

COSMIC

<https://cosmicmedical.ca>

Public Invention

<https://www.pubinv.org/>

JOGL - Just One Giant Lab

<https://jogl.io/>

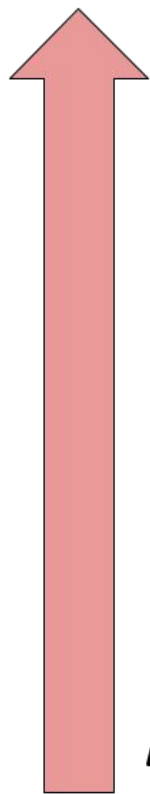
Enormous spread of knowledge to engineers

- About 100 engineers now fully understand mechanical ventilation
- Significant spread of knowledge about licensing, but still tremendous confusion
- Many hardware engineers learned about remote team organization and agile techniques pioneered by software engineers

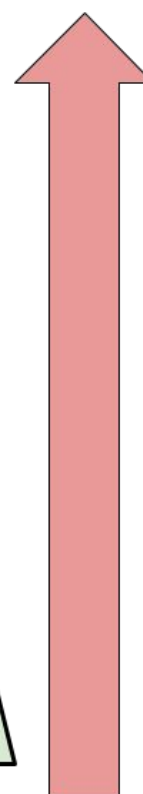
Why Free/Open Source Medical Devices?

- Eventually, a Free-libre medical device should be MORE trustworthy because all of the testing is transparent.
- The expensive research capital for basic medical devices has long since been the basis of sunk business costs and profits.

Cost of
Development



Licensing
Complexity



Medical Devices

No specific license yet

Hardware

E.g. CERN, but questions

Software

GPL, Affero, and permissive: MIT, etc.

Text

E.g., CC0, CC-SA

Things that were bad

- Great confusion about FLOS licensing
 - Persistent and groundless fear of liability based only on design
 - Much confusion on copyleft vs. permissive licensing
 - Multiple licenses create paradox of choice
- “Open” -- but not right now...and then it is too late!!
 - Tremendous duplication of effort due to lack of transparency
 - Being free and open from day one would have helped this
- Benefits of open source community slow to be evidenced...
 - Reuse of hardware a little bit harder than software
 - Everyone wanted to be “the” solution

Lessons of the Great Ventilator Rush

1. Think not of being THE solution, but A PART of the solution.
2. Be modular as the Free Software community is.
3. Learn from the Free Software team organization techniques.
4. Engineering is not enough on a hardware team; organization, fundraising, management, and user experience is even more important than on a software team.
5. The communication burden is about three times that of a pure software team.
6. An free culture medical device movement is born and growing.
7. Licensing and liability require some thought; we advocate separating development from manufacturing.
8. Respect the FDA (and other) regulatory processes.

Think not of being THE solution, but a PART of the solution.

In the 2020 ventilator rush, 100 teams worked almost in isolation.

By being free and open earlier, they would have allowed discovery more easily and reduced duplication of effort.

Bucky: “Tell the truth, tell the whole truth, and tell it right now.”

Me (and Eric Mill): “Be free and open from the first day of the project.”

The “We’ll eventually be open” mindset is a terrible mistake that I heard on many occasions.

Be humble. **Composability >> Modularity**

Be composable as the Free Software community is.

AFAIK, the UNIX design principle started it: you write small programs (filters) which can be composed to do useful things.

Today, we use JSON as a de-facto standard, but the Free Software community (and git, and github, and Savannah and the FSF) have created a practice of making small, composable software units.

This is NOT true of medical devices, and is only partially true of microelectronics in general.

Learn from the Free Software team organization techniques.

- Source control systems most of all---from day one!
- Unit testing.
- Automated Tests and Continuous Deployment.
- Agile development beats big design up front---even for medical devices.

The Difficulty of Measuring Impact: Even worse in Hardware.

Who is building your device? “Views and downloads” are unlikely to correlate to outside builds.

Engineering is not enough on a hardware team; organization, fundraising, management, and user experience is even more important than on a software team.

Free software led free hardware---understandably.

Capital costs for any hardware start at \$100s and quickly become \$1,000s. This is a significant psychological impediment. (The non-profits try to help, but not enough!)

Copying software is free; copying hardware is not! You may need multiple prototypes to employ the team.

BUT---IoT helps, and video chat helps.

Doing a good job designing the user experience is typically harder than software.

The communication burden is about three times that of a pure software team.

Even with video chat, text chat, etc., communication is much harder on a team building a physical device.

Teaching students to debug a circuit with a multimeter over video chat is non-trivial.

A free-libre open-source medical device movement is born and growing.

Good news: there is a tiny but growing Free Culture medical device movement.

Licensing and liability require some thought; we advocate separating development from manufacturing.

Medical devices are harder to deploy than hobby devices which are harder to make than software.

The world needs a free culture medical device license which triggers on the act of applying for regulatory approval.

Marc and I have started [SunlightRegulatory](#), a project to create such a license.

Designs do not create liability; statements asserting fitness for use do. Do not fear publishing Free designs; fear exaggerations.

Respect the FDA (and other) regulatory processes.

There are no shortcuts.

A regulatory environment imposes additional burdens which are time-consuming.

My suggestions:

- Plan on it taking more time.
- Plan on having to learn the rules.
- Do not exaggerate the cost of the paperwork: it is expensive but not prohibitively so.
- But, we currently have no Free-libre community and culture that knows how to do this.

Done with Lessons.

A Personal Idea: Respireco

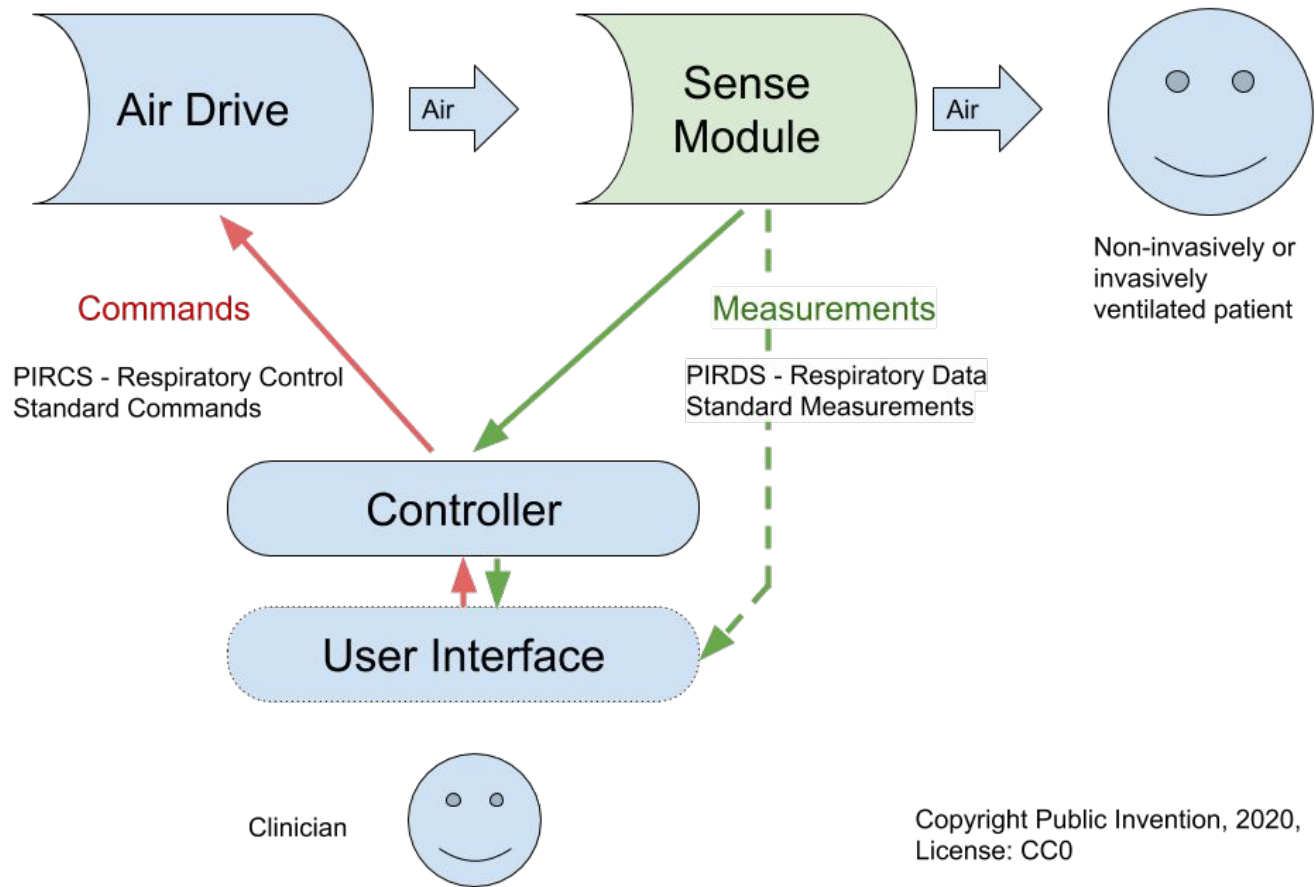
“**R**espiration **E**cosystem” of “**R**esearch **A**spiration **C**ompany”

Complete Free-Libre Modular Respiration System

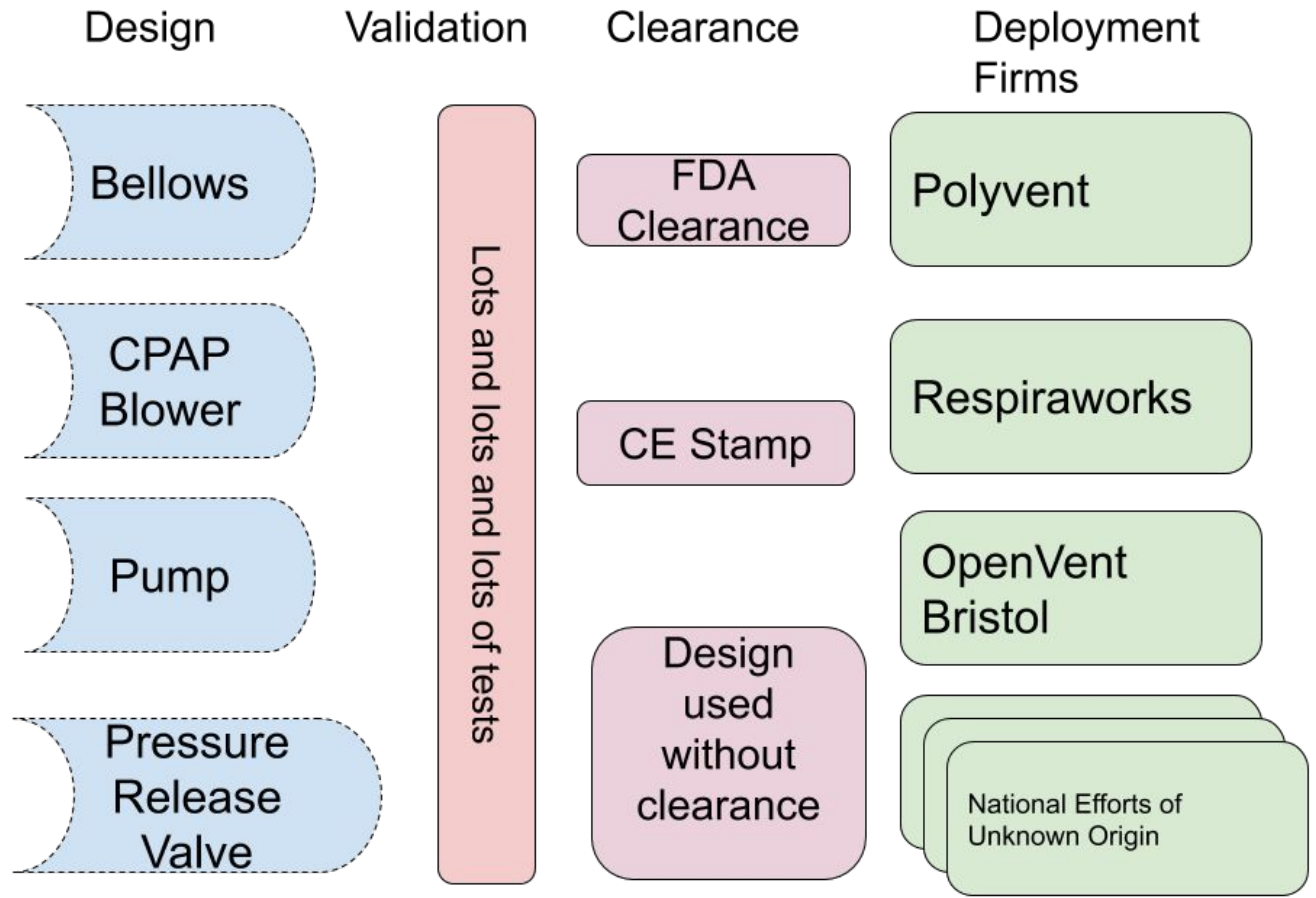
Goal is to obtain the “net effect” on the components: total value is the square of the number of complete components. This is harder to do in hardware than software, but not impossible.

This makes it easier for free culture software and hardware engineers to contribute, because there are many composable projects.

Composability >> Modularity



Social Organization



Pandemic Projects as Part of the Ecosystem

1. [VentMon](#)
2. [Public Invention Respiration Data Standard](#)
3. [VentDisplay](#)
4. [VentMon Data Lake](#)
5. [VentOS \(a Helpful Engineering Project\)](#)
6. [Public Invention Oxygen Concentrator](#)
7. [SFM3X00](#)
8. [Patient Inflating Valve](#)
9. [MedDev License](#)

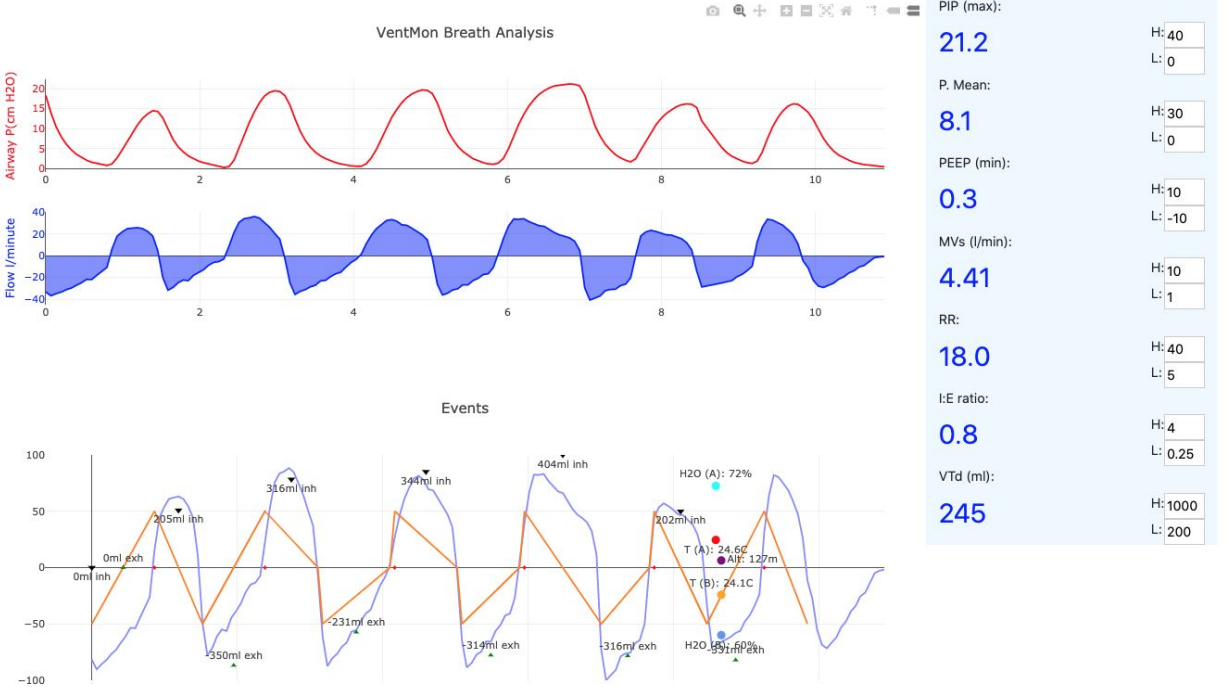
Standards (PIRDS) and VentDisplay allow teamwork.

PIRDS data server url: Use Ventmon Data Lake:

Trace ID:

Number of samples to Read and Plot:

Plot Live:



VentMon T0.4 shipping! Gratis to Libre teams!



Regulatory Sunlight License: A new kind of Free Culture License

- Covers ALL documentation sent to the FDA
- Allows reuse of that documentation
- Triggers on application to regulatory body
- Goal is to (over decades) create a shared public commons of reusable device designs, documentation, tests, risk analyses, manufacturing plans, incident reports, etc.
- We could use competent legal, political economy, graphic art, and scholarship help:
- <https://github.com/PubInv/RegulatorySunlight>

We ask you to reify this Vision:

“Twenty years from now, medical devices will be abundant because there will be an internationally distributed supply chain of transparently and publicly testable free culture medical devices.”

“Invent in the public, for the Public.”

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